

**Remarks**

Claims 1 and 3-15 are pending in the application. Claims 16-102 have been cancelled. The Examiner has rejected claims 1 and 3-15.

**Claim Rejections under 35 U.S.C 103(a)**

The Examiner has rejected claims 1 and 3-15 as being obvious under 35 U.S.C 103(a) over Fiddian-Green (US 6,334,064). This rejection is respectfully traversed and reconsideration is requested.

The Applicant has made amendments to the claims of the instant Application to clarify the Applicant's claimed invention. The claim amendments should not be considered an acceptance of the Examiner's obviousness rejection by the prior art and do not raise new issues for consideration.

Claim 1 as amended recites an implantable surgical drain for placement against a tissue of a patient's body for draining fluid and sensing at least one physiological property of the tissue comprising: an elongated conduit configured to be implanted in a patient's body to drain fluid from tissue of the body, the elongated conduit including a first and a second surface on an outer side of the elongated conduit; a sensing element positioned on the first surface of the conduit configured to sense a physiological property of the tissue; and an inflatable compartment positioned behind the sensing element and configured to push the sensing element against the tissue to enhance contact between the sensing element and the tissue.

Fiddian-Green does not teach or suggest all of the claim limitations. MPEP 2143. Specifically Claim 1 requires "an inflatable compartment positioned behind the

sensing element to push the sensing element against the tissue and to enhance contact between the sensing element and the tissue." The inflatable compartment is configured to enhance the contact between the sensing element and the tissue by bulging behind the sensing element, thereby pushing the sensing element against the adjacent tissue as shown in figures 13A-F. Fiddian-Green does not teach or suggest this feature.

The Examiner alleges that the membrane 36 of Fiddian-Green is configured to optimize contact between the first sensing element and the tissue (Fig. 1 and column 5, Lines 6-8, 16). The cited figure and the passage do not show or teach the inflatable compartment being positioned behind the sensing element to push the element against the tissue. It merely shows a balloon-like membrane 36 that encloses the catheter's distal end assembly, including the sensors 42 as shown in figure 1 of the reference. In Fiddian-Green, the element in contact with the tissue is the membrane 36, not the sensors 42. In contrast to the Examiner's statement, the sensors (42) in Fiddian-Green do not contact with the tissue. Therefore, Fiddian-Green does not teach the Applicant's claimed inflatable compartment that is configured to enhance the contact between the sensing element and the tissue.

The Examiner nevertheless states that "the conventional balloon catheter is well known in the art and comprises at least one balloon that is disposed inside a lumen and subsequently inflated to anchor the catheter in place" (Page 3, 2<sup>nd</sup> paragraph, lines 3-5). However, even these conventional devices did not use an inflatable compartment to urge a sensing element against tissue. Thus, a key element of amended claim 1 is still missing from both Fiddian-Green and the conventional catheter balloon cited by the

Examiner. An obviousness rejection cannot be maintained when the cited prior art fails in combination to teach all of the elements of the invention. See, e.g., M.P.E.P. 2142 ("To establish a *prima facie* case of obviousness, . . . the prior art reference (or references when combined) must teach or suggest all the claim limitations.")

The Examiner also fails to cite any motivation or suggestion in the prior art for modifying the device in Fiddian-Green to place its sensors on the outside of its balloon. Indeed, there is no suggestion in Fiddian-Green that its sensors 42 would even work better if urged in contact with surrounding tissue. To the contrary, it appears that they would not work. An obviousness rejection also cannot be maintained when the prior art fails to suggest the modification required by the patent claim. See, e.g., M.P.E.P. 2142 ("To establish a *prima facie* case of obviousness, . . . there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings").

Therefore, Claim 1 is allowable over Fiddian-Green and the conventional balloon catheter.

Regarding claim 3, the Examiner alleges that the balloon membrane 36 of Fiddian-Green is configured to fit within the conduit 22. However, the Examiner fails to cite any text or figure in Fiddian-Green that discloses such a configuration. In fact, it is contrary to what the Examiner stated with respect to claim 1 above. (The Examiner acknowledged that the membrane 36 of Fiddian-Green is fitted over the closed end of elongated tubing (See office action page 3, 2<sup>nd</sup> paragraph).) The present claimed invention requires the inflatable compartment to be within the elongated conduit and

behind the sensor element. Fiddian-Green neither teaches nor suggests this feature. Therefore, claim 3 is allowable over Fiddian-Green.

Claims 4-10 depend from allowable independent claim 1 and are thus allowable.

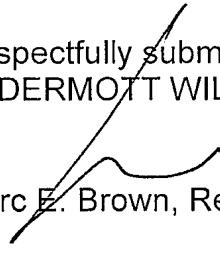
The Examiner has rejected claims 11-15 over Fiddian-Green in view of Wittes et al. (US 3,680,562); Torre et al. (US Patent Application 20020055757) or Schoolman (US 5,215,539). None of these references remedy the shortcomings of Fiddian-Green as discussed above with respect to claim 1.

## CONCLUSION

The Applicant respectfully submits that the above remarks place this application in a condition for allowance, which the Applicant respectfully solicits.

A petition for a two-month extension of time under 37 C.F.C. 1.136 is being filed contemporaneously herewith. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 501946 and please credit any excess fees to such deposit account and reference attorney docket no. 64693-103.

Respectfully submitted,  
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